K113454

FEB 2 4 2012

3. 510(k) Summary

510(k) Summary

510(k) Owner:	Micro Therapeutics d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No. 2029214
Contact Person:	Gregory J. Geissinger Manager, Regulatory Affairs Telephone: (949) 297-9781 E-mail: ggeissinger@ev3.net
Date Summary Prepared:	10 February 2012
Trade Name of Device:	14 Wire Standard Hydrophilic Guidewire & 14 Wire LS Hydrophilic Guidewire
Common Name of Device:	Catheter Guidewire
Classification of Device:	DQX, Catheter Guidewire (21 CFR 870.1330), Class II
Predicate Devices:	0.014" Transend EX Platinum Guidewire (K971254) 0.014" Transend EX Guidewire (K964611)
Device Description:	The 14 Wire is a stainless steel guidewire with a radiopaque distal segment. The distal portion of the guidewire is hydrophilically coated. Included within the sterile pouch is a torque device to assist in guidewire manipulation and a guidewire introducer to ease the introduction of the guidewire into the catheter hub and/or hemostasis valve.
Intended Use:	The 14 Wire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral and cerebral vasculature during diagnostic and/or therapeutic procedures. The device is not intended for use in the coronary arteries. The Guidewire Torque Device is intended to facilitate guidewire manipulation during interventional procedures. The Guidewire Introducer is intended to facilitate guidewire insertion into a catheter hub or through a hemostasis valve.
Non-Clinical Performance Data:	Biocompatibility testing, extensive bench testing, and an in vitro design validation study were performed as well as shelf-life testing and an assessment of bioburden, pyrogen, EtO residuals, and sterility.

Non-Clinical Tests

- Visual Inspection
- Dimensional Inspection
- Tip Flexibility
- Tip Buckling Force
- Torque Response
- Tip Shapeability
- Tip Shape Retention
- Flexing Test
- Coating Adherence
- Navigation
- Kink Resistance
- Torque Strength
- Tensile Strength
- Coating Lubricity
- Fracture Test
- Corrosion Resistance

Conclusion:

The 14 Wire is substantially equivalent to the 0.014" Transend EX and EX Platinum Guidewires based on the successful completion of non-clinical testing, identical principles of operation and nearly identical indications for use, as well as similarities in the design, materials, dimensions, accessories, packaging, and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Micro Therapeutics, Inc.
c/o Mr. Gregory J. Geissinger
Manager, Regulatory Affairs
9775 Toledo Way
Irvine, CA 92618

FEB 2 4 2012

Re: K113454
Trade/Device Name: 14 Wire Standard Hydrophilic Guidewire & 14 Wire LS Hydrophilic Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: February 10, 2012
Received: February 13, 2012

Dear Mr. Geissinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M.A. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2. Indications for Use Statement

Indications for Use

510(k) Number (if known): K113454

Device Name: 14 Wire Standard & 14 Wire LS

Indications for Use: The 14 Wire Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral and cerebral vasculature during diagnostic and/or therapeutic procedures. The device is not intended for use in the coronary arteries.

The Guidewire Torque Device is intended to facilitate guidewire manipulation during interventional procedures.

The Guidewire Introducer is intended to facilitate guidewire insertion into a catheter hub or through a hemostasis valve.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M.C. Hollenbeck

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113454